

6 June 2002



# MURGITROYD & COMPANY

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**ADVANCE COPY BY FACSIMILE - 01993 868 844 - SEVEN PAGES ONLY**

Dear Tim

**United States of America Patent Application No 09/869700**

**Richard A Henry**

**Catch: Topical Anesthesia of the Urinary Bladder**

**IP Title: "Topical Anesthesia of the Urinary Bladder"**

We have now received a final Official Action in connection with this Application. A copy of the Official Action is enclosed. As this Official Action has been marked **FINAL**, the Application must be in order for acceptance before **7 August 2002**. An extension of up to three months may be obtained beyond that date, but will incur extra costs.

The Examiner has maintained his objection that all Claims are obvious over the cited prior art. Claims 1, 3 to 13 and 16 are considered to be non-inventive over Higson et al. or Sethia et al., and Claim 14 is considered to be non-inventive over Higson et al. or Sethia et al. in combination with Askin. ☐

REDACTED

...Cont'd/

## Exhibit 2



Murgitroyd & Company Limited, Registration No. 144082 (Scotland)  
MURGITROYD is a Registered Trade Mark

INTERNATIONAL PATENTS, TRADE MARKS, REGISTERED DESIGNS AND COPYRIGHT

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MURGITROYD  
& COMPANY

Page 2

6 June 2002

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/Cont'd...

I look forward to receiving your instructions.

Yours sincerely  
for Murgitroyd & Company

**BEVERLEY OUZMAN**  
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Enc: Copy Official Action

cc: Mike Wyllie, Urodoc - 01227 365 563  
Mr Richard Henry - lynchris@sympatico.ca  
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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,700	09/04/2001	Richard Henry	03000018AA	8542

7590 05/07/2002

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8830-17 164535

EXAMINER

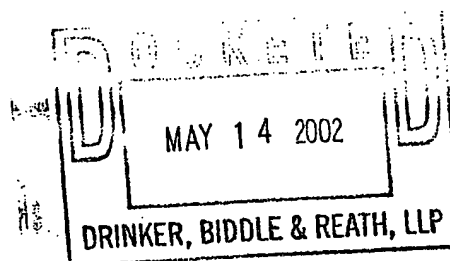
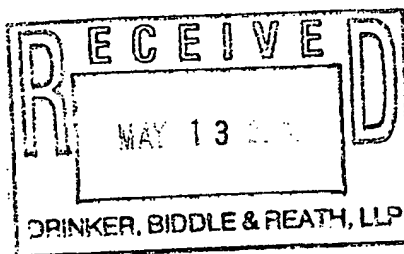
REAMER, JAMES H

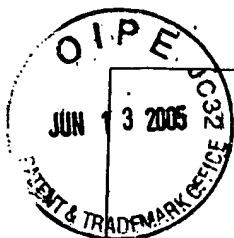
ART UNIT PAPER NUMBER

1614

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.





## Office Action Summary

Application No.	Applicant(s)	
09/869,700	HENRY, RICHARD	
Examiner	Art Unit	
James H. Reamer	1614	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

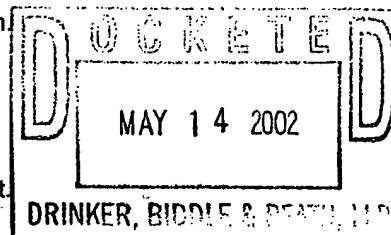
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.



### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

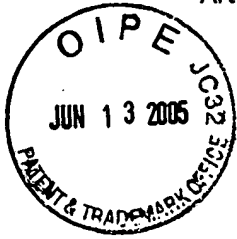
### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

Art Unit: 1614



**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3 to 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higson et al or Sethia et al, of record, for the reasons of record. Applicant's arguments have been considered but are not deemed persuasive since there is insufficient evidence that the separate addition of the lignocaine and alkalizing agent produces unexpected results. Higson et al on page 502 discloses that the means of diffusion of the lignocaine through the tissue is well known, the base form being diffused more rapidly than the salt form. Moreover, Sethia et al teaches the addition of the alkaline solution followed by the addition of the lignocaine, page 517, and column 2. The instant claims do not have any order of addition for the two solutions. In addition, the instant claims broadly claim the use of any type of local anesthetic in combination with an alkalizing agent and there is no proof that other types of local anesthetics produce improved results when used by the claimed procedure. The claims remain rejected absent additional evidence that the claimed procedure produces unexpected results to the extent claimed.

Claim 14 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Higson et al or Sethia et al in combination with Askin, for the reasons of record. The above arguments apply equally to claim 14 since this claim differs from the previous claims by limiting the claim to the treatment of interstitial cystitis which is shown to be treated by a local anesthetic. The use of an alkalizing agent to increase the rate of diffusion would be obvious from the teachings of the two primary references.

Claim 1 as amended is incomplete; the first line of the claim was not included in the amendment. Correction of the omission is required with any subsequent response.

**Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Reamer whose telephone number is (703) 308-4461. The examiner can normally be reached on 5:30 AM to 2:00 PM Monday-Thursday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Application/Control Number: 09/869,700

Page 4

Art Unit: 1614

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-3909.

  
James H. Reamer  
Primary Examiner  
Art Unit 1614

JHR  
May 6, 2002